AMENDED IN ASSEMBLY JUNE 8, 2006

AMENDED IN ASSEMBLY JUNE 20, 2005

AMENDED IN SENATE MAY 26, 2005

AMENDED IN SENATE MAY 23, 2005

AMENDED IN SENATE MAY 9, 2005

AMENDED IN SENATE MARCH 17, 2005

SENATE BILL No. 163

Introduced by Senator Scott
(~~Coauthor: Senator Kuehl~~ *Coauthors: Senators Chesbro, Ortiz, and Romero*)
(Coauthors: Assembly Members Frommer, Laird, Lieber, Koretz, Oropeza, and Pavley)

February 8, 2005

~~An act to add Section 10295.2 to the Public Contract Code, relating to public contracts.~~ *An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information.*

LEGISLATIVE COUNSEL'S DIGEST

SB 163, as amended, Scott. ~~Public contracts.~~ *Pharmaceutical information: clinical trial data.*

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available every initiated and ongoing clinical trial, except a phase I trial, the results of every completed clinical trial, except a phase I trial, and an explanation of noncompletion for any uncompleted clinical trial, except a phase I trial, that the company conducts or sponsors.

~~Existing law establishes various requirements applicable to entities that contract with the state.~~

~~This bill would require a pharmaceutical company, as defined, entering into a contract with an agency of the state to disclose the percentage of its national operating budget that is expended on marketing purposes, and the percentage of its national operating budget expended on research and development, with specified exceptions. The bill would prohibit a state department or agency from entering into a contract with a pharmaceutical company in the absence of that disclosure. This bill would authorize a pharmaceutical company to request that confidential or proprietary information so disclosed be held confidential and would make findings regarding the interest protected by keeping this information confidential.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~yes~~ *no*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) Recent scandals involving Vioxx, Celebrex, Paxil, and other medications have demonstrated a need for the state to better protect California consumers taking pharmaceutical products.

(2) In some of these scandals, including Vioxx and Paxil, the manufacturers of the drugs had access to clinical trial data demonstrating serious potential adverse side effects or lack of effectiveness, but the manufacturers did not share the data with the general public.

(3) The absence of this information hurts consumers both financially and physically. Research by the federal Food and Drug Administration estimates that Vioxx alone may have caused

up to 140,000 cases of coronary heart disease in the United States.

(4) Articles and editorials in leading medical journals and newspapers have highlighted problems with clinical trial reporting beyond outright data suppression, including: the use of a comparison drug at a dosage that is too low to be effective, making the study drug appear superior; the choice of a comparison drug dosage that is too high, making the study drug appear less toxic; the publication of data only from preferential endpoints; the publication of the same data in multiple articles to increase the data's impact; and the use of ghostwriters paid indirectly or directly by the study sponsor to give the sponsor control over the publication's message.

(5) By making sure that clinical studies on pharmaceutical drugs see the light of day and that the information necessary to understand and critique the studies is available, doctors and other medical professionals will be better equipped to make sound decisions about medicines and patients will be better informed about potential dangers of certain medicines.

(b) It is the intent of the Legislature in enacting this act to require pharmaceutical drug companies to make public the results of clinical trials conducted on their drugs if those drugs are made available to California consumers.

SEC. 2. Division 112.6 (commencing with Section 130650) is added to the Health and Safety Code, to read:

DIVISION 112.6. PHARMACEUTICAL DRUG RIGHT-TO-KNOW ACT

130650. This division shall be known, and may be cited as the "Pharmaceutical Drug Right-to-Know Act."

130651. For purposes of this chapter, the following definitions shall apply:

(a) "Adverse events" means any negative health outcome occurring in a clinical trial subject during the course of the clinical trial.

(b) "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects.

(c) "Comparator drug" means an investigational or marketed drug or placebo against which a new drug is being tested and compared.

(d) "Completion date" means the date of the last patient visit necessary for completion of the trial or the date of the first publication of any data from the clinical trial, whichever is first.

(e) "Initiation date" means the date of enrollment for the first patient in a clinical trial.

(f) "Pharmaceutical company" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of pharmaceutical drugs, either directly or indirectly, by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of pharmaceutical drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a pharmaceutical drug in this state on behalf of a pharmaceutical company.

(g) "Pharmaceutical drug" means any drug which is approved by the federal Food and Drug Administration and commercially available in the state.

(h) "Phase I trial" means the initial studies designed exclusively to determine the metabolism and pharmacologic actions of drugs in humans, and the side effects associated with increasing doses, and to gain early evidence of effectiveness.

(i) "Principal sponsors" means the entity ultimately responsible for funding the trial, the entity ultimately responsible for designing the trial protocol, and the entity who owns the data generated by the trial.

(j) "Purposes of the trial" means the hypotheses that the trial is testing, including, but not limited to, all of the following:

(1) The drug's effectiveness in treating a specific illness or condition. In this case, the illness or condition shall be named, and what type of effect is being sought shall be specified.

(2) The drug's safety when used to treat a specific illness or condition. In this case, the illness or condition shall be named.

(3) The relative effectiveness or relative safety of the drug in treating a specific illness or condition as compared to another

drug. In this case, the illness or condition shall be named, and the effect or adverse events to be compared shall be specified.

(k) "Outcomes of the trial" means the specific measurements that were taken to evaluate the effects the drug and any comparator drug had on trial participants.

(l) "Outcomes to be tested" means the specific measurements that will be taken to evaluate the effects the drug and any comparator drug have on trial participants.

(m) "Trial funding sources" means the name of and financial contribution amount for each organization, corporation, individual, or other entity that provides any funding for the clinical trial.

130652. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, every initiated and on-going clinical trial, except a phase I trial, that the company conducts or sponsors for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for registration shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs to be tested, including comparator drugs, if any.

(c) Dosages to be tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation date and expected completion date of the trial.

(e) Purposes of the trial, including the medical condition or conditions to be studied.

(f) Outcomes to be tested, including all time points at which outcome data will be measured.

(g) Trial funding sources.

(h) Number of participants to be enrolled in the trial.

(i) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(j) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(k) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(l) Any other information required for clinical trial registration by section 113 of the federal Food and Drug Administration Modernization Act of 1997.

130653. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, the results of every completed clinical trial, except a phase I trial, that the company has conducted or sponsored for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information necessary to meet this requirement shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs, if any.

(c) Dosages tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation and completion dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Outcomes of the trial including all time points at which outcome data were measured.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients completing the trial.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(l) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial.

(o) If any of the data from the study were published in any form, a complete citation and, if available, a hyperlink for each of these publications.

(p) If any of the data from the study were published, the name and employer of each author of the study, including "ghostwriters." For purposes of this section, "employer" shall mean the employer at the time the trial was conducted and the trial results were prepared and published.

(q) Any financial interest the principal researchers of the study have in the drugs tested or compared in the trial and in the principal sponsors of the trial. For purposes of this section, "financial interest" shall be considered within the time period between when the trial was conducted and the trial results were prepared and published.

(r) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130654. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, an explanation of noncompletion for any clinical trial, except a phase I trial, that the manufacturer initiates but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for an explanation of noncompletion shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs, if any.

(c) Dosages tested for each drug including dosages of comparator drugs, if any.

(d) Initiation and termination dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Reasons for termination of the trial.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients enrolled in the trial on the termination date.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, and preexisting health conditions and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(l) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants, including participants that dropped out of the trial for any reason, prior to the termination date.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial prior to the termination date, for each drug.

(o) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130655. The information required pursuant to Sections 130652, 130653, and 130654 shall be submitted for inclusion on www.clinicaltrials.gov, the Web site administered by the National Institutes of Health pursuant to section 113 of the federal Food and Drug Administration Modernization Act of 1997, or its successor Web site, subject to all of the following conditions:

(a) For clinical trials with a trial initiation date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to

www.clinicaltrials.gov no later than 21 days after the trial's initiation. For ongoing clinical trials with a trial initiation date before January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov on or before January 22, 2007.

(b) For clinical trials with a trial completion date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130653 to www.clinicaltrials.gov or its successor Web site no later than 90 days after the trial's completion. For clinical trials with a completion date before January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130653 to www.clinicaltrials.gov or its successor Web site on or before April 1, 2007. The publication information required in subdivisions (o) and (p) of Section 130653 shall be updated no later than 21 calendar days from publication, whenever data from the trial have been included in a new publication. If the trial was registered when it was initiated, any differences between the information reported at that time and the information being submitted upon completion shall be highlighted and explained.

(c) For clinical trials with a noncompletion date on or after January 1, 2007, the sponsor of the trial shall submit the information required by Section 130654 to www.clinicaltrials.gov no later than 21 days after the trial's noncompletion. For clinical trials with a trial noncompletion date before January 1, 2007, the sponsor of the trial shall submit the required information to www.clinicaltrials.gov on or before January 22, 2007.

130657. All information submitted pursuant to this division shall be in plain English to the maximum extent possible, with the goal of being readily understandable by a person who is not a medical professional.

130658. Nothing in this division shall constitute a duty by the State Department of Health Services to enforce the implementation of this division.

~~SECTION 1. Section 10295.2 is added to the Public Contract Code, to read:~~

~~10295.2. (a) A pharmaceutical company entering into a contract with a state department or agency shall disclose to the Legislature and to the chief of the department or agency~~

~~secretary, the percentage of its national operating budget that is expended for marketing purposes, and the percentage of its national operating budget that is expended for research and development purposes. No state department or agency may enter into a contract with a pharmaceutical company in the absence of that disclosure. This disclosure shall be made 30 days prior to the effective date of the contract and annually thereafter. The following marketing expenses are not subject to the requirements of this section:~~

~~(1) Expenses of twenty-five dollars ($25) or less.~~

~~(2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, or treatment.~~

~~(3) Scholarships and reimbursement of expenses for attending a significant educational, scientific, or policymaking conference or seminar of a national, regional, specialty medical, or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.~~

~~(4) Drug samples given to physicians and health care professionals intended for free distribution to patients.~~

~~(b) For the purposes of this section, the following definitions apply:~~

~~(1) "Marketing" means activities associated with advertising, marketing, and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail, and telephone in connection with detailing or promotional activities performed by the company directly, or through its pharmaceutical marketers.~~

~~(2) "Pharmaceutical company" means:~~

~~(A) An entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.~~

~~(B) An entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.~~

~~(C) A person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state on behalf of a pharmaceutical company.~~

(D) “Pharmaceutical company” does not include a licensed pharmacist or a licensed wholesaler, as defined by Section 4043 of the Business and Professions Code.

(3) “Research and development” means any activity that is undertaken for the purpose of discovering information that is technological in nature, the application of which is intended to be useful in developing a new or improved business component, including any product, process, computer software, technique, formula, or invention that is to be held for sale, lease, or license, or for use in the company’s trade or business. The activity shall constitute elements of a process of experimentation and shall be conducted for the purpose of relating to a new or improved function, performance, reliability, or quality.

(c) (1) Notwithstanding any other provision of law, any person required to present information to the Legislature and contracting department or agency pursuant to this section may request that confidential or proprietary information be held in confidence. The Legislature and contracting department or agency shall grant the request under any of the following circumstances:

(A) The information is exempt from disclosure under the California Public Records Act, Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.

(B) On the facts of the particular case, the public interest served by not disclosing the information clearly outweighs the public interest served by disclosure of the information. If it is determined that the disclosure of the information will result in an unfair competitive disadvantage to the person supplying the information, then the information shall not be disclosed.

(2) The contracting department or agency may, by regulation, designate certain categories of information as confidential and thereby remove the obligation to request confidentiality for that information. Information that has already been made available to the public through another public entity shall not be designated as confidential.

(3) The Legislature and contracting department or agency shall not grant the request if the information has already been made available to the public through another public entity.

(4) The contracting department or agency shall disclose information obtained pursuant to this section that has not been

~~designated as confidential on its Web site to facilitate greater public disclosure.~~

~~SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 10295.2 to the Public Contract Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:~~

~~Information provided under Section 10295.2 may contain sensitive business information, the disclosure of which will result in an unfair competitive disadvantage to the person supplying the information.~~

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